



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/100,633	06/19/98	HUTCHENS	T 016866-00220

HM22/1208
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EXAMINER

WESSENDORF, T

ART UNIT	PAPER NUMBER
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1618

10

DATE MAILED:

12/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/100,633

Applicant(s)

Hutchens et al

Examiner

T. Wessendorf

Group Art Unit

1618



☒ Responsive to communication(s) filed on Nov 12, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 25, 26, 30, and 33-69 is/are pending in the application.

Of the above, claim(s) 34, 35, 37-41, 43-45, 47, 48, 50-53, 55-57, 59-62, 65, and 66 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25, 26, 30, 33, 36, 42, 46, 49, 54, 58, 63, 64, and 67-69 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Applicant's election without traverse of Group IV, claims 25-26 and 30-35 in Paper No. 8 is acknowledged.

A telephonic restriction was made on 11/29/99 with respect to an species restriction as follows:

1. Adsorbent

A). Small Organic Molecule

B). Biopolymers

I). Cell

ii). Cell membrane

iii). Virus

iv). Virus

v). Chemically derivatized chemical group

vi). Nucleic acid

vii). Peptide

viii). Fusion protein

Each of these species differ structurally and functionally. Each of the species would require different patentability determinations under the different statutes. A prior art search with respect to one species would not render obvious the other species.

2. Target Analyte

A). Cell surface receptor

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B). Glycoprotein

C). Antibody

Each of these species differ structurally and functionally. Each of the species would require different patentability determinations under the different statutes. A prior art search with respect to one species would not render obvious the other species.

3). Library

A. Peptide

B. Antibody

C. Gene Package

D). Carbohydrate

E). Lectin

Each of these species differ structurally and functionally. Each of the species would require different patentability determinations under the different statutes. A prior art search with respect to one species would not render obvious the other species.

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

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inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with J. Storella on 11/99 a provisional election was made with traverse to prosecute the invention of the species peptide for the adsorbent and target analyte and peptide library. The claims that read on the elected species are: 25-26, 30, 33, 36, 42, 46, 49, 54, 58, 63-64, 67-69.

Affirmation of this election must be made by applicants in replying to this Office action.. Claims 34-35, 37-41, 43-45, 47-48, 50-53, 55-57, 59-62 and 65-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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The use of the trademarks e.g., TWEEN at page 15, line 21 and Figure 9 and TRITON at page 78, line 4 have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are requested to further check for other trademarks used in the specification since they are too numerous to mention specifically.

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 30, 33, 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 25 is confusing as to the whether the adsorbent comprises a polypeptide agent i.e., whether an agent is attached to said adsorbent. This is inconsistent with the disclosure which disclose the polypeptide and agent as two different or discrete entities.

B). The recitation in claim 25 of a polypeptide agent is inconsistent with the recitation in claim 30 of simply an "agent". The use of inconsistent terminology to mean the same(?) thing provides for confusion and ambiguity within the claimed context. It is requested that applicants be consistent in the use of the

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different terminologies. For example, it is not clear whether the adsorbent is made up of only a polypeptide or a polypeptide adsorbent with the attached or coated (polypeptide) agent. Furthermore, it is not clear as to how screening is done when the agent specifically reacts with the target analyte. It is suggested that applicants incorporate the limitation of claim 33 to claim 30.

C). The method of screening in claim 33 of a combinatorial library broadens the base claim which does not recite for screening a library of agents. Furthermore, it is not clear, within the claimed context, whether the agents binds to the polypeptide present in adsorbent or to the target analyte.

D). The method step of claim 33(b) is confusing as to the exclusive binding of the target analyte and the adsorbent i.e., to the exclusion of the agent (the polypeptide agent?) and adsorbent binding.

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E). The term "whereby" is superfluous and merely provides for confusion as to the intent of said term, within the claimed context.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent No. 5,719,060 ('060 Patent).

Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the '060 Patent encompasses the instant substrate comprising an adsorbent comprising a polypeptide agent. The instant substrate is recited at claim 13 of the '060 Patent and the adsorbent, polypeptide is included in the broadly recited probe of claim 12.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 25-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either Hutchens et al (WO 94/28418) or Kauvar (WO 89/09088).

The claimed substrate comprising an adsorbent that comprises a polypeptide agent is anticipated or obvious over the substrate of Hutchens at e.g., page 59, line 20 up to page 60, line 25; page 95, claim 40 up to page 96, claims 41-42 lines 13-20. See the substrate disclosed by Kauvar at e.g., page 5, lines 23-31; page 14, lines 7-35.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35-USC 103, jointly or alternatively, the burden of proof is the same

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as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

Claims 30, 33, 36, 42, 46, 49, 54, 58, 63-64 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kauvar in view of Hillenkamp et al (5,118,937).

Kauvar discloses a method of screening a polypeptide agent that modulates binding between a target analyte and adsorbent comprising reacting the substrate to the target analyte and detecting an amount of binding between the target analyte and adsorbent containing polypeptide and measuring the amount of binding in the presence or absence of a modulating agent except the measurement of binding is not done by desorption spectrometry, as recited. However, Hillenkamp discloses the advantages derived in the use of a desorption spectrometry for large biomolecules. See e.g., the abstract. Accordingly, it would have been obvious to one having ordinary skill in the art at

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the time the invention was made to measure the binding affinity in the method of Kauvar with a desorption spectrometer for the advantage disclosed by Hillenkamp.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Schwarz et al disclose a chromatography adsorbents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

12/6/99

T. Vezady
Patent Examiner
